NHS
Essex Partnership University
NHS Foundation Trust

INTRODUCTION

Formulary and Prescribing Guidelines

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The Trust's Medicines Management Group aids prescribers by evaluating the evidence for new and existing drugs, and making recommendations on therapies on clinical and economic grounds. Where appropriate, restrictions on the use of particular drugs may be recommended.

The Formulary and Prescribing Guidelines (F&PG) is about those drugs approved for use within Essex Partnership University NHS Foundation Trust (EPUT) by the Medicines Management Group (MMG).

The primary purpose of the formulary is to recommend preferred drug treatments for commonly-encountered clinical conditions, in order to rationalise the range of products used within the organisation. The drugs recommended in this formulary have been selected on the basis of their efficacy and side-effect profiles relative to other drugs in the same therapeutic class. If there are a number of drugs of similar efficacy and safety within the same class, the NHS price will also be taken into consideration when determining which products to include within the formulary. Prescribers should always refer to the latest edition of the BNF or Summary of Product Characteristics (SPC) for information regarding dosages, contraindications and side effects.

This document also aims to be a source of advice and guidance on best clinical practice, from both local and national perspectives. In particular, it is important that it should reflect the recommendations contained within the NICE Clinical Guidelines (CGs) and Technology Appraisals (TAs), since the Trust has a duty to ensure that local clinical practice is compliant with NICE. Information from other acknowledged psychiatric sources including the British Association of Psychopharmacology, The Maudsley Prescribing Guidelines and the Psychotropic Drug Directory are also considered.

The F&PG is designed to be a dynamic document used electronically with links available to relevant appendices, sections and annexes allowing efficient access to relevant information. Links to external sites and documents e.g. NICE CGs and TAs, have also be inserted for convenience of the reader. Whilst every attempt will be made to ensure the information contained within this document is accurate, readers are always encouraged to ensure they use the most up to date information sources to aid clinical decision making. All comments and suggestions should be forwarded to epunft.askpharmacy@nhs.net.

NICE has published recommendations[1] for practitioners involved in making decisions regarding individuals who lack capacity or supporting decision-making in individuals who have capacity, to follow the 5 key principles set out in section 1 of the Mental Capacity Act 2005. As a starting point they must assume capacity unless there is evidence to suggest an assessment is required.

When giving information about a decision to the person:

• it must be accessible, relevant and tailored to their specific needs

• it should be sufficient to allow the person to make an informed choice about the specific decision in question

• it should be supported by tools such as visual materials, visual aids, communication aids and hearing aids, as appropriate

NICE has also published specific recommendations[5] for decision making in patients under the age of eighteen. An example of a visual aid to support decision making in young people is shown in Appendix 1.

NICE has also published general recommendations[6] on shared decision making. This covers how to make shared decision making part of everyday care in all healthcare settings. It promotes ways for healthcare professionals and people using services to work together to make decisions about treatment and care. It includes recommendations on training, communicating risks, benefits and consequences, using decision aids, and how to embed shared decision making in organisational culture and practices.

NICE has published recommendations on safe prescribing and dispensing in the management of self-harm. This recommends that healthcare professionals should use consultations and medicines reviews as an opportunity to assess self-harm, asking about thoughts of self-harm, suicide, actual self-harm and access to substances that might be taken in overdose.

When prescribing medicines to someone who has previously self-harmed or who may self-harm in the future, healthcare professionals should take into account:

- the toxicity and pharmacokinetic properties of the prescribed medicines for people at risk of overdose
- their recreational drug and alcohol consumption, the risk of misuse, and possible interactions with prescribed medicines
- the person's wider access to medicines prescribed for themselves or others
- the need for effective communication where multiple prescribers are involved.

Shared decision making should be used to discuss limiting the quantity of medicines supplied to people with a history of self-harm.

The F&PG is designed to help the practitioner with such decision-making, and includes examples of such appropriate tools.

CLASSIFICATION OF DRUGS

Formulary Drugs

Drugs approved by the MMG for use within the Trust which have proven efficacy and supporting evidence.

Non-formulary drugs

Drugs that are new to the market, have unsubstantiated benefits, have significant cost implications or have serious adverse effects are included in this category. Also in this category are drugs that offer no advantages over existing similar drugs. They are not stocked in pharmacy and should not be routinely prescribed. However, they may be made available in exceptional circumstances e.g. if a patient has been maintained on the drug for some time or if a consultant wishes to try a drug for an individual patient before requesting inclusion in the formulary. Submissions for non-formulary drugs to be added to the Formulary should be made to the MMG using the paperwork contained in Appendix 5 of CLPG13, annex 1. Non-formulary drug requests for individual patients should be made using annex 2 and forwarded to the chair of the MMG for consideration. Detailed information regarding non-formulary medication can be found in CLPG13.

Restricted

Some drugs are required to be initiated by a consultant or under his/her direct instruction. These drugs tend to require specialist knowledge and/or monitoring.

Off-label use of licensed drugs

In psychiatry, clinicians frequently prescribe licensed drugs for indications that are not covered by the terms of their marketing authorisation (product license). In this situation, liability for any adverse consequences arising from treatment rests with the clinician and the Trust rather than with the manufacturer.

The table below lists unlicensed indications/off-label uses for UK licensed drugs, which are acknowledged by the Medicines Management Group as representing acceptable clinical practice. Many of these unlicensed indications (off-label use) are well-established in clinical practice, and have a sound basis in published data. Provided there is a reasonable body of medical opinion supporting the use of a drug for an unlicensed indication, the clinician and the Trust would be able to defend themselves against a claim (Bolam principle). Additional counselling will need to be provided to the patient as the indication for which the agent is being used will not be acknowledged within the patient information leaflet.

If a clinician wishes to use a licensed product off label that is not listed below, they are advised to seek the approval of the MMG using the paperwork contained in Appendix 4 of CLPG13. Submissions should be made to the chair of the MMG along with any supporting evidence for consideration. (Readers are referred to CLPG13 for guidance relating to the

request of a drug which **does not hold** a UK product licence and/or new drugs which are currently non-formulary)

Off label/unlicensed indication	Drug(s) approved by EPUT MMG	Evidence of safety and efficacy, or evidence of concerns
Alcohol abstinence	Naltrexone	
Alcohol withdrawal	Oxazepam	
Antipsychotic induced Akathisia	benzodiazepines, clonidine, cyproheptadine, propranolol	
Antipsychotic induced Hypersalivation	hyoscine hydrobromide, atropine	
Antipsychotic induced Tardive Dyskinesia	tetrabenazine	
Antipsychotic-induced Hyperprolactinaemia:	amantadine, bromocriptine	
Antipsychotic-induced Hypotension	fludrocortisone	
Acute psychosis / agitation / mania:	lorazepam, clonazepam, diazepam, midazolam,	
Agitation / aggression in brain injury	beta blockers, carbamazepine, valproate, promethazine	
Anorexia	Olanzapine	
Acute anxiety	Promethazine (oral)	Licensed for insomnia, short-term (7 days), but no published evidence for anxiety. Can cause significant cognitive impairment in dementia. A lack of clear anxiolytic effects militates against longer-term use. [2]
Acute agitation	Promethazine (oral / IM)	Listed in Maudsley guidelines for rapid tranquilisation. [2] Listed in BAP rapid tranquilisation guideline as “recommended” [3].
Insomnia	Melatonin capsules unlicensed Circadin® used off label	
Aggressive/impulsive behaviour	carbamazepine, sodium valproate, naltrexone	
Behaviour problems in autism/LD	antipsychotics	
Benzodiazepine withdrawal	Diazepam	
Bipolar affective disorder	antipsychotics (see note below), lamotrigine, gabapentin, valproate	
BPAD rapid cycling	clozapine, lamotrigine, thyroid hormones, clonazepam	
Behavioural & Psychological Symptoms of Dementia	lorazepam, trazodone, clomethiazole, carbamazepine, sodium valproate, antipsychotics, AchE inhibitors	

Off label/unlicensed indication	Drug(s) approved by EPUT MMG	Evidence of safety and efficacy, or evidence of concerns
Borderline personality disorder (crisis)	Sedative antihistamine, e.g. promethazine.	Short-term use of sedative medication (e.g. promethazine) may be considered cautiously as part of the overall treatment plan for people with borderline personality disorder in a crisis. Choose a drug with a low side-effect profile, low addictive properties, minimum potential for misuse and relative safety in overdose, use the minimum effective dose, prescribe fewer tablets more frequently if there is a significant risk of overdose, agree the target symptoms, monitoring arrangements and anticipated duration of treatment, agree a plan for adherence, discontinue a drug after a trial period if the target symptoms do not improve, consider alternative treatments, including psychological treatments, if target symptoms do not improve or the level of risk does not diminish, arrange an appointment to review the overall care plan, including pharmacological and other treatments, after the crisis has subsided. The duration of treatment should be agreed, but should be no longer than 1 week. After the crisis undertake a review drug treatment with the patient, including benefits, side effects, any safety concerns and role in the overall treatment strategy. Discuss plan to stop drug treatment begun during a crisis, usually within 1 week. If drug treatment started during a crisis cannot be stopped within 1 week, there should be a regular review of the drug to monitor effectiveness, side effects, misuse and dependency. The frequency of the review should be agreed and recorded. Sedative antihistamines are not licensed for this indication and informed consent should be obtained and documented.[4]
Cataplexy in narcolepsy	clomipramine, fluoxetine, fluvoxamine, paroxetine	
ECT augmentation	to reduce threshold: antipsychotics, to increase duration: caffeine, theophylline	
GAD	Sertraline	
Hyperkinetic disorder / ADHD (adult):	clonidine, tricyclic antidepressants, fluoxetine, risperidone	
Hypersalivation with clozapine	Pirenzepine (Gastrozepin®) import (unlicensed)	
Insomnia	trazodone, mirtazapine	
Opiate withdrawal	Clonidine	

Off label/unlicensed indication	Drug(s) approved by EPUT MMG	Evidence of safety and efficacy, or evidence of concerns
Refractory depression:	dexamethasone, lamotrigine, pindolol, thyroid hormones, high dose venlafaxine (> 375mg/day), clozapine	
Refractory PTSD:	Clonidine	
Refractory schizophrenia	lamotrigine	
Sexual dysfunction (due to SSRIs):	Cyproheptadine	
Tics	clonidine, pimozide, risperidone, sulpiride	

Note:

Antipsychotics in bipolar affective disorder.

1. Antipsychotics may be used off-label for the treatment of bipolar affective disorder where this use is well-established in clinical practice. This use does not require the prescriber to submit an application for off-label use.

2. Some antipsychotics have a licensed indication for bipolar affective disorder for the **oral** form, but not for the intramuscular depot or long-acting injection (LAI) form. Where this is the case the intramuscular depot or LAI form may be used for treatment of bipolar affective disorder, and does not require the prescriber to submit an application for off-label use.

References

1. NICE guideline NG108: Decision-making and mental capacity. Published October 2018.

2. The Maudsley Prescribing Guidelines in Psychiatry 13th edition (2018).

3. British Association for Psychopharmacology and the National Association of Psychiatric Intensive Care and Low Secure Units. Joint BAP NAPICU evidence-based consensus guidelines for the clinical management of acute disturbance: de-escalation and rapid tranquilisation. 2018. Journal of Psychopharmacology, 1 - 40.

4. NICE CG78. Borderline personality disorder: recognition and management. Published date: January 2009

5. NICE guideline NG204: Babies, children and young people's experience of healthcare. Published: 25 August 2021.

6. NICE guideline NG197: Shared decision making. Published: 17 June 2021.

7. NICE guideline NG225: Self-harm: assessment, management and preventing recurrence. Published: 7 September 2022.

Appendix 1: Visual summary setting out how to use NICE guidelines on young people's experience of healthcare.